K093476

510(K) Summary (per 21 CFR 807.92)

FEB - 5 2010

1. **Applicant Information**

Date Prepared:	November 6, 2009
Submitter:	AGA Medical Corporation 5050 Nathan Lane North Plymouth, MN 55442 USA
Establishment Registration Number:	2135147
Contact person:	Diane Carroll Regulatory Affairs Associate Telephone Number: 763.531.3161 Fax Number: 763.647.5932

2. **General Device Information**

Trade Name:	AMPLATZER® TorqVue® 2 Delivery Sheath
Common Name:	Catheter, Delivery Sheath
Classification Name:	Catheter, Percutaneous
Classification:	Class II, 21 CFR 870.1250
Product Code:	DQY
Predicate Device:	AMPLATZER® TorqVue® Delivery System, K072313, cleared November 2, 2007 Reg. No. 870.1250

3. **Device Description**

The AMPLATZER® TorqVue® 2 Delivery Sheath is a sterile, single-use, general-purpose sheath that is an extension of the TorqVue Delivery System product line. It is designed to provide a pathway through which a device may be delivered to the peripheral vasculature.

The AMPLATZER® TorqVue® 2 Delivery Sheath has a usable length of 120 cm and is available with a 5 Fr, 6 Fr, or 7 Fr inner diameter. A dilator, which eases penetration of tissue, is packaged with each sheath. The distal

end of both the sheath and dilator are straight. The body of each sheath is radiopaque for visibility under fluoroscopy.

The single-lumen sheath is constructed of two segments of different polyether block amide (Pebax®) materials to provide support for device advancement and tip flexibility for vessel engagement. The Pebax® encapsulates a stainless-steel braid support structure that provides maneuverability while minimizing kinking. The distal end of the sheath has a soft tip composed of 55-durometer Pebax® to minimize vessel trauma.

4. **Intended Use**
   The AMPLATZER® TorqVue® 2 Delivery Sheath is intended to provide a pathway through which devices are introduced within the peripheral vasculature.

5. **Comparison to Predicate**
   The AMPLATZER® TorqVue® 2 Delivery Sheath has the following similarities when compared to the predicate device:
   - Indications for Use for the TorqVue 2 Delivery Sheath are a subset of the TorqVue Delivery System
   - Operating principal is the same
   - Manufacturing materials and processes are similar
   - Sterilization method is the same
   - Sterile package materials are the same

6. **Test Data**
   The functional characteristics of the AMPLATZER® TorqVue® 2 Delivery Sheath are substantially equivalent to the predicate devices cited. Bench testing of the AMPLATZER® TorqVue® 2 Delivery Sheath included visual and dimensional inspection, resistance to kinking due to bending, freedom from leakage of air and liquid, tensile strength, device interaction testing, and distribution simulation.

7. **Summary**
   Based on the technical information, intended use, and laboratory verification test information provided, the AMPLATZER® TorqVue® 2 Delivery Sheath is substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

AGA Medical Corporation
c/o Ms. Diane Carroll
Regulatory Affairs Associate
5050 Nathan Lane
Plymouth, MN 55442

FEB - 5 2010

Re: K093476
AMPLATZER® TorqVue® 2 Delivery Sheath
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 06, 2009
Received: November 09, 2009

Dear Ms. Carroll:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

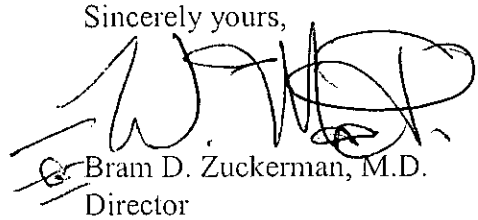
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K093476

Device Name: AMPLATZER TorqVue 2 Delivery Sheath

Indications for Use: The AMPLATZER TorqVue Delivery Sheath is intended to provide a pathway through which devices are introduced within the peripheral vasculature.

Prescription Use ___X___ **AND/ OR** **Over-The-Counter-Use** _____
(Part 21 CFR 801 Subpart D) **(Part 21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K093476